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Producers of Quality Nonprescription Medicines and Dietary Supplements for Self-Care

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket Nos. 02N-0276, 02N-0277, 02N-0278, and 02N-0275: 2002 Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL107-188).

The Consumer Healthcare Products Association (CHPA)[1] submits these comments in response to Joseph A. Levitt's letter to the food industry, dated July 17, 2002 regarding FDA's response to Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL107-188)(hereinafter "the Act"). These comments are a compilation of the comments we received from our members who manufacture dietary supplements and those who source raw materials for use in dietary supplements both from foreign sources and from here in the United States. As we have prepared one set of comments to cover all four topics, i.e., registration, record keeping, prior notice, and detention, these comments are being filed to the following four dockets:

Section 303: Administrative Detention	Docket No. 02N-0275
Section 305: Registration of Food Facilities	Docket No. 02N-0276
Section 306: Establishment and Maintenance of Records	Docket No. 02N-0277
Section 307: Prior Notice of Imported Food Shipments	Docket No. 02N-0278

[1] Founded in 1881, CHPA is a trade organization representing the manufacturers and distributors of national and store brand dietary supplements and nonprescription medicines. CHPA's membership includes over 200 companies involved in the manufacture and distribution of these self-care products and their affiliated services (e.g., raw material suppliers, research testing companies, contract manufacturing companies, advertising agencies, etc.).

GENERAL COMMENTS

CHPA requests that CFSAN consider the following when drafting the proposed regulations:

- **Definition of Food:** The Act amends various provisions of the existing Food, Drug & Cosmetic Act (FD&C Act), which already defines the term "food." 21 U.S.C. §321(f). Additionally the FD&C Act also defines the term "dietary supplement," and prescribes that for most purposes, a dietary supplement shall be deemed to be a food within the meaning of this [FD&C] Act." *Id*. at § 321(ff). Thus, it is clear that the provisions of the Act that relate to food are generally intended to cover dietary supplements as well. However, what is less clear is how those provisions may translate into actual implementation of the law, particularly in those areas in which dietary supplements differ from conventional foods in their manufacturing, distribution and usage. The regulations should clearly spell out and provide examples of how various provisions relate to dietary supplements.

  With respect to potential food ingredients, CHPA suggests that ingredients should be regulated by intent. Sections 301-315 of the Act should be applied only to food and ingredients intended for use in food. Ingredients intended for use in anything other than foods (cosmetics, laundry detergents, OTC drugs, medical devices, etc.) should not be regulated under these Sections even if the ingredient could be used in a food or even if the ingredient is commonly used in other applications as a food. Consistent with the other aspects of the FD&C Act, manufacturer's intent should be the basis for determining if a particular ingredient shipment is subject to these Sections. If an ingredient like an FD&C dye is shipped to a facility for use in only cosmetic products, then the facility receiving the dye can consider that dye shipment to be cosmetic (and not a food ingredient) -- even if the facility selling the dye is a registered food facility and sells dyes to other sites for food use.

- **Utilization of Existing Records.** CHPA strongly encourages FDA to implement this Act making maximum use of records and systems that already exist. Using or linking to existing systems will substantially lessen the economic impact of the Act for FDA and industry, encourage cross-agency coordination, and increase the likelihood of high compliance from the onset. Required records for food manufacturing, processing and packaging should be consistent with cGMPs for foods as well as the proposed GMP rulemaking for dietary supplements, anticipated for later this year. However, FDA access to these records needs to be limited to specific issues. For example, where current U.S. Customs Service records can be used to assist with Prior Notice requirements, they should be. In addition, FDA should try to minimize disruptive impacts on existing post-9/11 cooperative efforts such as the U.S. Customs-Trade Partnership Against Terrorism (C-TPAT), developed to facilitate cross-border shipments of products.

- **Confidentiality of Records.** Sections 305, 306, and 307 of the Act provide FDA with the authority to obtain records. Materials obtained by FDA under this authority are very likely to include records marked Confidential. FOI protections are enhanced in some, but not all, Sections of the Act despite access to similar records. We strongly encourage FDA to evaluate how record access protections in one section of the Act may correspond to the protections of another section. Further, the issues of electronic signatures on submitted documents and maintaining the security of these signatures will need to be addressed.

- **Exemption for Research and Development Activities.** Facilities conducting food product -- including dietary supplement -- research and development (R&D) should be exempt from the requirements of Sections 305, 306, and 307 of the Act. Food R&D facilities typically maintain small quantities of many different "food" ingredients. Use of these materials is most commonly documented in research notebooks as part of new product development. Information contained therein includes formula development records, analytical methods development, consumer preference testing, and product performance testing, and clinical trails conducted with the intent of bringing a new product or process to market. Product development trials and consumer research are typically small-scale tests conducted under controlled conditions. Therefore, exempting R&D activities appears consistent with the intent of the Act.

- **Implementation of the Act.** When the provisions of Section305, 306 and 307 of the Act become effective in December 2003, we recommend FDA grandfather any product or ingredient that is already in the "distribution chain". Some dietary supplement and their ingredients may be stored for several years. Even with 18 months of lead-time, the receipt of some of these ingredients will predate passage of the Act. Records such as country of origin, and previous ownership simply may not exist.

SECTION 303: ADMINISTRATIVE DETENTION:

- **Handling of Disputes and Dispute Resolution:** Any regulations with respect to detention of product should spell out how disputes and resolutions will be handled expeditiously in order to help prevent spoilage of detained food and dietary supplements. In addition, the regulations should also address the mechanism for the possession of the material during detention. Many botanicals are particularly sensitive to moisture and humidity, and some ingredients like vitamin C are susceptible to light. Consideration should be given to prevent the needless deterioration of product.

SECTION 305: REGISTRATION OF FOOD FACILITIES:

- **Definition of Facility:** CHPA recommends a clear definition of facility that is consistent with the record keeping requirements of the Act. CHPA believes a facility

should mean a fixed, enclosed structure or structures controlled by a single owner, operator or agent. We believe a company should be permitted to designate a single building as a facility, designate two or more adjacent buildings as a facility, or designate two or more buildings in close proximity as a facility. Similarly, we believe two adjacent/close proximity buildings with different US postal addresses could still be designated a single facility, even if a company owns one and rents the another.

- **Exclusion of Transportation Vessels/Vehicles in the Definition of Facility:** CHPA recommends excluding vehicles and containers used solely to transport food products between facilities from the definition of facility. Otherwise, the requirements could be construed as requiring each railcar, airplane, ship, car, shipping container and truck to be registered separately. On the other hand, vehicles or containers used to process, manufacture or package food products would be considered facilities subject to registration.

- **Definition of Other Retail Establishments**: Consistent with the intent of the Act, CHPA believes a building that only ships food products directly to consumers (either by mail or by carrier) should be considered to be an exempt "other retail food establishment", not a nonexempt warehouse. Similarly, we conclude a facility that ships 60% of its business direct to consumers would still be considered an "other retail food establishment", even thought 40% of its business is wholesale shipment. A 40%/60% distribution would make the facility a warehouse, subject to Act requirements.

- **Disposition of Food Previously Held by an Unregulated Facility.** The law notes that it is a prohibited act to fail to register. If a firm learns that a food product has been stored, prepared, packaged, or held at a facility that has not been registered with FDA, what happens to that food product? Can the firm help get the unregistered facility registered and then continue using the product? Does this require an immediate notification to the Agency? Does FDA have to give a formal concurrence before the food can be used? Must the food be destroyed? We believe this occurrence will happen in everyday commerce and FDA needs to have a process to register the facility so that food is not needlessly destroyed.

- **Access/Confidentiality of Registration Records.** The Act gives FDA access to facility names, facility addresses, trade names and "when determined necessary" the general food category of any food in the facility. The Act also states the identity or location of a specific registrant will be exempt from public disclosure. This suggests that not all trade name data and general food category will be protected. Access to the unprotected information may be more useful for illicit use than the protected information. It may also be sufficient for someone to logically deduce the information not provided (through an EPA database for example), defeating the intent

of the Act. FDA should therefore consider what information warrants protection in the context of other US Agency databases.

- ***De Minimus* Exclusion for Sampling Activities.** While domestic facilities engaged in manufacturing, processing, packing, or holding food are required to register, only the last facility located outside the US in which food is processed or packaged is required to register. This means that other foreign firms can subsequently handle product prior to export to the US without registering. In some cases, these firms may inspect or sample product. We believe sampling needs to be a formally recognized *de minimus* activity. Sampling in this context is not a manufacturing, processing, or packing activity and adds to the assurance of product quality by validating certain product attribute(s) prior to shipment. In addition, foreign facilities that conduct *de minimus* activities should not be prohibited from registering.

- **Amending Registrations.** While initial facility registration is a one-time event, companies are responsible for providing FDA with timely amendments when changes are made. Registration information includes facility name, facility address, and trade names and "when determined necessary" the general food category of any food processed, packaged, or held at the facility. While it makes sense to immediately, notify FDA if a facility changes name, ownership, or address, does FDA really want notification each time a new food trade name is started at a facility or discontinued at a facility? We believe FDA ought to make annual or biannual electronic message requests to ask for facility trade name changes or direct mail/fax requests for registered facilities without electronic messaging capabilities.

- **Need for Separate Registration as a Food Facility.** Facilities manufacturing drugs are already required to register with FDA as Drug Establishments under the FD&C Act. If these same facilities already registered with the agency, also manufacture a dietary supplement, would they also be required to register as a food establishment? Such duplication seems unnecessary because FDA is already aware of the facility's existence.

SECTION 306: ESTABLISHMENT AND MAINTENANCE OF RECORDS

- **When Does Record Keeping Start?** The Act requires records to be maintained to allow FDA to identify the immediate previous source and immediate subsequent recipient of food and food packaging to address credible threats. For a US company importing product, where does this requirement formally start? Is it the first receipt of product in within the United States? Is it when a US subsidiary in a foreign country receives the product before import into the US? Is it when a company takes ownership FOB when the product is loaded on the shipping vessel and the vessel leaves port? We suggest the first US facility (the first fixed enclosed structure in the US that product is held) is the correct location for record keeping requirements to commence.

- **What Records Should be Maintained?** The Act requires maintenance of records to allow FDA to identify the immediate previous source and immediate subsequent recipient of food and food packaging in order to address credible threats. It also gives FDA access to manufacturing and packaging records. To facilitate compliance with the requirements, two record keeping principles should be kept foremost in mind. These are 1) the regulations should encourage use of existing data and systems; and 2) FDA access to records should be limited to the current issue of protecting Americans from threats to the integrity of food products resulting from bioterrorism. Rather than create new requirements, use of existing U.S. Customs, shipping and FDA systems should be facilitated whenever they are sufficient.

  The following records appear to be sufficient to identify the immediate previous source and immediate subsequent recipient of food and food packaging in order to address credible threats: product brand name (if any), product common name, product identification number, name and address of site product is being shipped from, name and address of site product is shipped to, name and address of carrier. We believe cGMPs should provide adequate records of food processing, manufacturing and packaging; however, FDA access to records should be limited to the scope of a specific FDA investigation.

- **Record Keeping For Tolling Operations And Futures Exchanges.** Some commodity food products can be bought and sold on Futures Exchanges. In these cases, product "ownership" and actual product possession are usually separate. Product may not even be in the US while the commodity is being bought and sold. In tolling, the titleholder's identity is not known by the processor. In both these situations, tracking product movement appears more consistent with the provisions of the Act than tracking product title.

- **Manufacturing Site Record Specificity.** Some manufacturing operations are not conducive to linking incoming records to records of outgoing finished product. These legitimate processes are often either continuous operations or batch operations where different lots of incoming ingredients are commingled or blended. The result is a loss of specificity. In these cases, it is impossible to directly link use of 200 pounds of Ingredient X Lot 10 to 200 pounds of Finished Product Y Lot 65. Instead, site personnel may have a good idea that Ingredient X Lot 10 was likely in one of several lots of finished product. Under these circumstances, records, in combination with manufacturing site knowledge, should provide sufficient information for investigation by FDA.

- **Confidentiality of Food Manufacturing, Processing, and Packaging Records.** The Act provides FDA with access to all records needed to assist FDA in determining whether a food is adulterated and presents a threat of serious health consequences, including thorough factory inspections. The only prohibitions are sales data, recipes, financial and pricing data, personnel data and research data. That provides FDA a

wide scope of access without any added protections for confidentiality. Under previous law, only trade secrets are protected, however other valuable proprietary documents would not be protected. FDA should clearly communicate how they intend to treat proprietary information.

- **Lot Trace System.** Mulit-level-martketing (MLM) companies currently ship dietary supplement products from distribution centers directly to both their distributors and to consumers. They currently do not record the lot numbers of the products they ship, but ship each lot in FIFO (first in, first out) sequence. If these companies are required to record the immediate subsequent recipient, they will need to implement a lot trace system, similar to that used by the pharmaceutical industry, which will be a major expense. MLM companies with member direct ordering, currently have other means of contacting their distributors and their customers in the event of a terrorist act impacting one of their products, and therefore request that FDA take this under consideration when drafting the record keeping requirements section of the regulations.

- **Compliance of Record Keeping Requirements**. FDA should clearly outline in the proposed regulations what methods it will use to monitor compliance with the record keeping requirements. For example, will FDA use existing practices such as expanding the current food GMP inspections to include compliance with record keeping requirements or alternative methods?

- **Record Keeping for Raw Materials Sourced from Multiple Sources.** The degree of identification of raw materials can be an issue for large volume products, which use multiple sources. For example, vitamin E is extracted at ppm levels from vegetable oils and distillates, which is sourced as starting raw material from multiple manufacturers. An additional complicating factor is identifying the grain elevators which sourced a particular lot of oil which was in turn used to make the vitamin E.

- **Uniformity of Record Keeping.** FDA should spell out in the proposed regulations the degree of uniformity of record keeping be required by companies that have several hundred manufacturing, warehousing, and shipping locations around the world.

SECTION 307: PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS

- **Expedited and Simplified Systems.** For pre approved food products, FDA should develop an expedited process for prior consent. Based on the results of FDA's food product risk assessments and the companies involved with importing these products, FDA should allow development of a system for letting low risk products and low risk companies move quickly through import. Facilities outside the U.S. that employ cGMPs may also warrant expedited import procedures and timing.

- **Product Identification.** One of the required elements that must be provided to FDA before a food can be imported is the identity of the article. Since the system of giving prior notice for foods is likely to include both FDA and US Customs, using tariff codes may be a good starting point for identifying food products being imported. These codes would work well with some products as-is and could be amended to handle additional food detail.

- **Country of Origin.** Clear guidance is needed in regard to the prior notice requirement to provide the country from which the food product or food ingredient originates. Specifically, when a shipment is composed of a single agricultural product that has been grown in multiple countries and mixed in a single bin, what is its country of origin? When a product is processed and ingredients from several countries are combined, we believe this is a "substantial transformation" that makes the site of processing the country of origin, regardless of the source of the raw materials.

- **Shipment of Urgently Needed Raw Materials.** FDA should spell out exemptions to the regulations or modifications of the timelines under unusual circumstances. For example, the air shipment of urgently needed imported raw materials, specifically those with a short shelf life.

- **Existing Notification Practices and Time frames For Notifying FDA.** FDA should be mindful of existing notifications practices when drafting the proposed regulations and that shipments by air, water and land may require different notification time-frames. Specifically, <u>for air shipments</u>, notification of incoming imported shipments currently take place when the airplane takes off (wheel up clearance). The broker initiates Customs entry and is not allowed to initiate Customs entry before the plane takes off. If companies are required to notify FDA, per the default provision, at least 8 hours and not more than 5 days prior to a shipment, this could be a problem for any air shipment coming into the U.S. from Canada (1 hour flight time), from the U.K. (5 hours flight time), and from Mexico (5-6- hours flight time). FDA may need to create a prior notification method other than the standard entry filing through ABI, or insert a special clause for airfreight shipments. Because Section 801 of the FFD&C Act is being amended to add new 801(m), not only is there the potential for delay in the entry and receipt of the goods, but also there is the potential for additional costs in the way of accrued storage charges imposed by Customs/FDA for holding the goods until they receive the information they require, and/or the costs involved with the refusal of entry. This can also affect the time it takes for raw ingredients to clear customs and become available for the manufacture of finished products.

  Specifically, <u>for imports by ship</u>, there is an existing notification procedure whereby the shipment's manifest information is submitted to the Customs Department 72 hours before the ship's arrival in the U.S. and 96 hours before arrival to the U.S. Coast Guard. Currently, the ship must be within port limits when notification takes

place. The U.S. Coast Guard has proposed a ruling that will make permanent its 96-hour advance notice requirement for all cargo ships arriving in the nation's ports. Specifically, for shipment by truck, currently there is no prior notification for products coming into the U.S. by truck. We propose a *de minimus* notification requirement of at least one (1) hour notification for trucks with import shipments coming into the U.S. from countries like Canada.

In addition, some companies plan to participate in the proposed U.S. Customs Service C-PAT Program (Customs Trade Partnership against Terrorism). This is a joint government/industry initiative to build cooperative relationships that strengthen overall supply chain and border security. The objective of this system is to ensure the integrity of the security practice where companies meet certain requirements. Benefits include a reduced number of inspections; a membership list; an assigned account manager; and emphasis on self-policing.

- **Limitations of the OASIS System.** Companies are concerned about FDA's ability to handle large volume of data generated as a result of bioterrorism law and capabilities of the current OASIS system, which is an outdated system.

CONCLUSION

CHPA appreciates the opportunity to provide FDA with these considerations as it begins its awesome task in drafting the proposed regulations. As we have indicated during the Agency July 30 debriefing of the Act to our members, we would be willing to organize facility tours so that FDA gains an appreciation for the issues that our members have identified in these comments. Further, we recommend that an industry FDA partnership to assist in writing the regulations to share practical concerns and to ensure a more efficient, less burdensome system.

Sincerely yours,

Leila Saldanha, Ph.D., R.D.
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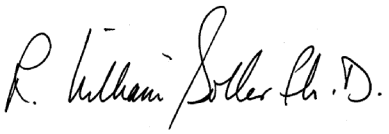

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